

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

UNITED STATES OF AMERICA, *et al.*,
ex rel. JOSEPH NOCIE,

Plaintiffs,

V.

STEWARD HEALTH CARE SYSTEM, LLC,
et al.

Defendants.

No. 18-cv-11160-WGY

THE UNITED STATES' OPPOSITION TO THE DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

For over nine years, the defendants¹ paid Dr. Arvind Agnihotri millions of dollars for his referrals to SEMC. Linking compensation to referrals violates the Physician Self-Referral Law, 42 U.S.C. § 1395nn (commonly referred to as the “Stark Law”). Congress enacted the Stark Law to outlaw schemes that could raise the cost of Medicare, distort medical decision-making, or impact market competition. Here, the unlawful compensation-for-referral arrangement with Dr. Agnihotri led SEMC to submit tens of millions of dollars of tainted claims to Medicare, despite SEMC’s falsely certifying compliance with the Stark Law. The government’s Complaint-in-Intervention (“Complaint”) details why the defendants’ knowingly violated the Stark Law by paying Dr. Agnihotri for his referrals, and why those violations resulted in violations of the False Claims Act (“FCA”), 31 U.S.C. §§ 3729–33, and federal common law.

In response, defendants argue that Dr. Agnihotri’s compensation arrangement fits various exceptions to the Stark Law or is close enough that the defendants did not know the difference. The defendants’ primary argument is that Dr. Agnihotri’s compensation arrangement is a “productivity bonus.” But there is no “productivity bonus” exception to the Stark Law for indirect compensation arrangements, such as the one at issue here. And the defendants’ arrangement did not reward “productivity”—it rewarded *referrals* to SEMC.

The government’s Complaint more than adequately pleads how SEMC’s indirect compensation arrangement with Dr. Agnihotri violated the Stark Law, and that the defendants knew better. It also leaves no doubt why the violations alleged here were material to CMS’ payment decisions. The Court, therefore, should deny the defendants’ motion to dismiss.

¹ Steward Health Care System, LLC (“Steward”); Steward Medical Group, Inc. (“SMG”); and Steward St. Elizabeth’s Medical Center of Boston, Inc. (“SEMC”) (collectively, the “defendants”).

FACTUAL BACKGROUND

Steward is a for-profit company that wholly-owns SMG and SEMC. Compl. ¶ 3. SEMC is a hospital in Brighton, Massachusetts. *Id.* ¶ 20. SMG provides medical services at SEMC and other locations. *Id.* ¶¶ 19–20. SMG employed Dr. Agnihotri. *Id.* ¶¶ 63, 68–69, 73–80. SEMC had an indirect compensation arrangement with Dr. Agnihotri. *Id.* ¶¶ 84–92.

In 2012, the defendants believed that the number of cardiac surgeries performed at SEMC was too low and endeavored to increase cardiac surgeries at SEMC. *Id.* ¶ 58. The defendants recruited Dr. Agnihotri and paid him incentive compensation that increased with the volume of his referrals to SEMC. *Id.* ¶¶ 59, 68–81. Notably, the defendants tied Dr. Agnihotri’s incentive compensation to his services that led to referrals to SEMC, and omitted any of his services that did not result in a referral to SEMC. *Id.* ¶¶ 104–11. In other words, the more surgeries Dr. Agnihotri referred to SEMC, the more he made. *See id.* ¶¶ 68–81, 104–11. The defendants ignored their own policies and procedures, trainings, and warnings from personnel, and entered into compensation arrangements with Dr. Agnihotri that they knew, or should have known, violated the Stark Law. *Id.* ¶¶ 133–54.

From January 1, 2013, through March 31, 2022 (the “Relevant Period”), SEMC submitted over 1,000 claims to Medicare for designated health services (“DHS”) Dr. Agnihotri referred. *Id.* ¶¶ 6, 160–63, Ex. 16. Hospitals, such as SEMC, are DHS entities. *Id.* ¶ 33 n.3. SEMC made false representations to Medicare that its claims complied with the Stark Law. *Id.* ¶¶ 164–69, Ex. 11. Relying on SEMC’s false representations of compliance with the Stark Law, Medicare paid SEMC tens of millions of dollars for these claims. *Id.* ¶ 161.

LEGAL STANDARD

When evaluating a motion to dismiss under Fed. R. Civ. P. 12(b)(6), the Court “must

assume the truth of all well-plead[ed] facts and give . . . plaintiff the benefit of all reasonable inferences therefrom.” *United States v. Regeneron Pharmaceuticals, Inc.*, No. 20-cv-11217, 2020 WL 7130004 at *7 (D. Mass. Dec. 4, 2020) (citations omitted). For FCA cases, the complaint “must state with particularity the circumstances constituting fraud” pursuant to Fed. R. Civ. P. 9(b). *United States v. Teva Pharmaceuticals USA, Inc.*, 560 F. Supp. 3d 412, 418 (D. Mass. 2021) (internal quotation marks omitted). “[O]ther elements of fraud, such as intent and knowledge, may be averred in general terms.” *Rodi v. S. New England Sch. of Law.*, 389 F.3d 5, 15 (1st Cir. 2004).

STATUTORY AND REGULATORY FRAMEWORK

The Stark Law. Congress passed the Stark Law in 1989 to help address the corrupting influence of money on medical decision-making and its impact on Medicare spending. Compl. ¶ 2. *Examining The Stark Law: Current Issues and Opportunities*, 114 Cong., S.Hg. 114-668 (Jul. 12, 2016) (stmt. of Troy A. Barsky), available at <https://www.congress.gov/event/114th-congress/senate-event/LC52008/text>. The Stark Law provides that CMS will not pay an entity for DHS referred by any physician having a “financial relationship” with that entity, unless that relationship satisfies the requirements of an applicable statutory or regulatory exception to the law. 42 U.S.C. § 1395nn(a)(1), (g)(1); see *United States ex rel. Drakeford v. Tuomey* (“*Tuomey I*”), 675 F.3d 394 (4th Cir. 2012). The Stark Law is a strict liability statute with no scienter requirement, and any amounts reimbursed by Medicare for services furnished in violation of the statute must be repaid. 42 U.S.C. § 1395nn(g)(2); 42 C.F.R. § 411.353(d); *Tuomey I*, 675 F.3d at 397–98. The Stark Law also does not require proof of overutilization. See *United States ex rel. Fischer v. Cmty. Health Network, Inc.*, No. 1:14-cv-01215, 2021 U.S. Dist. LEXIS 271155, at *25 (S.D. Ind. Oct. 20, 2021) (“[O]verutilization is not an element in the [Stark Law] statute.”).

To establish a *prima facie* violation of the Stark Law, the United States must show that: (1) an entity and a physician had a financial relationship; (2) the physician made DHS referrals to the entity; and (3) the entity submitted claims to Medicare for those services. 42 U.S.C. § 1395nn(a)(1). As relevant here, “financial relationships” include indirect “compensation arrangements,” and the Stark Law’s requirements and exceptions differ depending on whether the compensation arrangement is direct or indirect. 42 U.S.C. §§ 1395nn(a)(2), 1395nn(h)(1); 42 C.F.R. § 411.354(c)(2).

As relevant here, an indirect compensation arrangement exists if: (1) there is an unbroken chain of financial relationships between the physician and DHS entity; (2) the physician received aggregate compensation from their direct employer that varied with the volume or value of the physician’s referrals to the DHS entity; and (3) the DHS entity had knowledge that the referring physician received aggregate compensation that varied with the volume or value of referrals generated by the physician for the DHS entity. 42 C.F.R. § 411.354(c)(2); Compl. ¶ 84.

If the United States establishes a *prima facie* case, the burden shifts to the defendants to raise and prove, as an affirmative defense, that the financial relationship at issue satisfied all the requirements of an applicable statutory or regulatory exception. *Tuomey I*, 675 F.3d at 405 (“[T]he jury must further determine whether Tuomey could bear its burden of proof with respect to the indirect compensation arrangement exception.”); *United States v. Rogan* (“*Rogan I*”), 459 F. Supp. 2d 692, 716 (N.D. Ill. 2006).

The False Claims Act. The FCA establishes liability to the United States for any individual who, or entity that, “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” 31 U.S.C. § 3729(a)(1)(A), or “knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent

claim,” 31 U.S.C. § 3729(a)(1)(B). The FCA defines “knowingly” to include actual knowledge, reckless disregard, or deliberate ignorance of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.* Falsely certifying compliance with the Stark Law in connection with the submission of Medicare claims violates the FCA. *See* 42 U.S.C. § 1395nn(g)(1) (compliance with the statute is a condition of payment); *United States v. Rogan*, 517 F.3d 449 (7th Cir. 2008); *Tuomey I*, 675 F.3d at 396 n.2.

ARGUMENT

The government has more than adequately alleged violations of the FCA (counts I & II) and common law (counts III & IV) arising from SEMC’s violations of the Stark Law. The Complaint alleges SEMC violated the Stark Law because (1) SEMC and Dr. Agnihotri had an indirect financial relationship; (2) Dr. Agnihotri made DHS referrals to SEMC; and (3) SEMC submitted claims to Medicare for those services. 42 U.S.C. § 1395nn(a)(1).

The defendants effectively concede the government has met some Stark Law elements: they do not contest, nor could they, that Dr. Agnihotri made DHS referrals to SEMC or that SEMC submitted claims to Medicare for those services. ECF No. 97 at 8. The defendants, however, contend that the government has not alleged an indirect financial relationship because, they say, Dr. Agnihotri’s compensation did not vary with the volume or value of DHS referrals. As discussed below, that argument is unconvincing — as the Complaint alleges, the plain language of Dr. Agnihotri’s agreements show that his Incentive Compensation varied based on the number of cardiac surgical cases he performed at SEMC.

Furthermore, as discussed below, the Complaint adequately alleges that, because of SEMC’s Stark Law violations, the defendants are liable under the FCA and common law. The government has adequately alleged all necessary elements of its FCA claims — namely, that the

defendants submitted, or caused the submission of, false claims and statements within the meaning of the FCA; those violations were material to CMS because, among other things, the arrangement is the classic type of Stark Law violation that CMS and DOJ have made the subject of innumerable enforcement actions and rulemaking; and the defendants acted with scienter by ignoring concerns raised by their own executives, as well as their own policies, procedures, and trainings. The Court should deny Defendants' motion to dismiss its entirety.

I. The Government Has Adequately Pled a Stark Law Violation

The Complaint adequately alleges that SEMC violated the Stark Law. As mentioned above, the defendants do not contest that the United States has established two elements of a Stark Law violation: that Dr. Agnihotri made prohibited DHS referrals to SEMC, and that SEMC submitted claims to Medicare for services furnished pursuant to those referrals. Instead, the defendants argue that the government failed to plead that SEMC had an indirect financial relationship with Dr. Agnihotri. The defendants argue further that, if the government did plead such a relationship, the government failed to establish that the relationship did not satisfy the requirements of a Stark Law exception. Neither argument survives scrutiny.

A. The Complaint Adequately Alleges an Indirect Compensation Arrangement Between Dr. Agnihotri and SEMC

SEMC had an indirect financial relationship with Dr. Agnihotri because: (1) an unbroken chain of financial relationships existed between Dr. Agnihotri and SEMC, which included Dr. Agnihotri's employment arrangement with SMG, (2) Dr. Agnihotri received aggregate compensation from SMG (his direct employer) that varied with the volume or value of Dr. Agnihotri's referrals to SEMC, and (3) SEMC had knowledge that Dr. Agnihotri received aggregate compensation that varied with the volume or value of referrals Dr. Agnihotri generated for SEMC. Compl. ¶¶ 84–92, 148–54; *see* 42 C.F.R. § 411.354(c)(2). The defendants challenge

the last two elements, but the government has sufficiently pled both.

i. The Complaint Adequately Alleges the Volume or Value Element

The Complaint alleges in detail that Dr. Agnihotri’s direct employer, SMG, paid him aggregate compensation that varied with the volume or value of his referrals to SEMC. *See* Compl. ¶¶ 31–36, 58–120; Exs. 2–5. Dr. Agnihotri’s employment agreements with SMG plainly state that the defendants calculated Dr. Agnihotri’s Incentive Compensation in a manner that varied with the volume of his referrals to SEMC for cardiac surgeries by consistently and directly tying his Incentive Compensation to “the use of an operating room” at SEMC. Compl. ¶¶ 72–74, 78, 81; Compl. Exs. 2–5. The defendants made this point explicit in the Second Amendment to Dr. Agnihotri’s employment agreement: “[Dr. Agnihotri] shall receive as Incentive Compensation the amount listed below which corresponds to the number of surgical cardiovascular cases performed by the *St. Elizabeth’s Medical Center Division of Cardiac Surgery*.” (emphasis added) Compl. ¶ 78, Ex. 4. Dr. Agnihotri’s Incentive Compensation was unit-based (number of Surgical Cardiovascular Cases) and it varied with the volume of his referrals of DHS to SEMC.² Compl. ¶ 72; *see* 42 C.F.R. § 354(d)(2)–(3). Also, the defendants calculated Dr. Agnihotri’s Incentive Compensation using SEMC’s data on the number of Surgical Cardiovascular cases performed at SEMC, *not* based on any of SMG’s data regarding Dr. Agnihotri’s productivity. Compl. ¶¶ 113–16.

The defendants’ arguments on this point are misplaced insofar as they concern the *reasons why* Dr. Agnihotri’s Incentive Compensation varies with the value or volume of

² The DHS SEMC billed for the procedures Dr. Agnihotri performed at SEMC (that is, the “facility fees”) are the consequence of Dr. Agnihotri’s *referrals* to SEMC for purposes of the Stark Law. *See Tuomey I*, 675 F.3d at 406–7 (finding that the facility fee for the services performed by a physician is a referral within the meaning of the Stark Law).

referrals, and not just *whether* it so varies, which is all the government need plead to establish an indirect compensation arrangement. 42 C.F.R. § 411.354(c)(2). Defendants’ arguments, instead concern various inapposite Stark Law exceptions. *See* Part I.B.i., below.

ii. The Complaint Adequately Alleges the Knowledge Element of an Indirect Compensation Arrangement

The defendants’ only argument with respect to the knowledge element of indirect financial arrangements conflates that knowledge with scienter under the FCA. ECF No. 97 at 12–13; *Cf.* 42 C.F.R. § 411.354(c)(2) *with* 31 U.S.C. § 3729(b)(1). The Stark Law is a strict liability statute and does not require proof of scienter. 42 U.S.C. § 1395nn(g)(2); 42 C.F.R. § 411.353(d). To establish the knowledge element of an indirect compensation arrangement, the government need only plead that SEMC knew that Dr. Agnihotri received compensation from SMG that varied with the volume or value of his referrals to SEMC, which it has done. Compl. ¶¶ 84–92, 148–54. In any event, the government has met its burden for pleading scienter under the for FCA. *See* part I.C., below.

B. The Complaint Need Not Anticipate and Rebut Affirmative Defenses

The defendants argue that the government failed to plead that the indirect compensation relationship did not meet the requirements of an exception to the Stark Law. ECF No. 97 at 7–16. The defendants’ argument is procedurally mis-timed and should be rejected.

A defendant may attempt to prove compliance with an applicable Stark Law exception as an affirmative defense to alleged violations of the statute. But “[a] complaint states a claim on which relief may be granted whether or not some defense is potentially available, [which] ... is why complaints need not anticipate and attempt to plead around defenses.” *United States v. N. Tr. Co.*, 372 F.3d 886, 888 (7th Cir. 2004). Courts have repeatedly held that defendants in FCA cases predicated on Stark Law violations bear the burden of invoking and proving compliance

with an applicable Stark Law exception. *See Rogan I*, 459 F. Supp. 2d at 716 (“Once the United States has demonstrated proof of each element of a violation of the ... Stark [Law] ..., the burden shifts to the defendant to establish that his conduct was protected by a[n] ... exception; the United States need not prove, as an element of its case, that defendant’s conduct does not fit within a[n]...exception.”); *United States ex rel. Drakeford v. Tuomey* (“*Tuomey II*”), 792 F.3d 364, 374, 382 (4th Cir. 2015); *Tuomey I*, 675 F.3d at 398; *United States ex rel. Longo v. Wheeling Hosp., Inc.*, No. 5:19-CV-192, 2019 WL 4478843, at *4 (N.D. W. Va. Sept. 18, 2019); *United States v. Halifax Hosp. Med. Ctr.*, No. 6:09-CV-1002-ORL-31, 2013 WL 6017329, at *8 (M.D. Fla. Nov. 13, 2013); *United States ex rel. Parikh v. Citizens Med. Ctr.*, 977 F. Supp. 2d 654, 668 (S.D. Tex. 2013).

In the face of overwhelming precedent to the contrary, the defendants cite only to *United States ex rel. Witkin v. Medtronic, Inc.*, 189 F. Supp. 3d 259, 268 n.3 (D. Mass. 2016), in which another session of this Court, in a footnote, held that the relator did have to “negat[e] safe harbors,” to defeat the defendant’s motion to dismiss. The *Medtronic* Court recognized that in a Stark Law case a plaintiff need not negate exceptions at the pleading stage, but concluded that in a FCA case predicated upon the Stark Law, the pleading standard was different. 189 F. Supp. 3d at 268 n.3. The only authority cited by the *Medtronic* court in that footnote was *Rogan I*, which *was* a FCA case predicated upon a Stark Law violation, but reached the *opposite* conclusion to *Medtronic*. *See Rogan I*, 459 F. Supp. 2d at 716. *Medtronic* is not binding precedent on this Court, and is in direct conflict with numerous other cases to hold otherwise. *See, e.g., Tuomey II*, 792 F.3d at 374 (“Once a relator or the government has established the elements of a Stark Law violation, it becomes the defendant’s burden to show that the indirect compensation arrangement exception shields it from liability”). The government respectfully submits that to the extent

Medtronic can be read to require the government to negate exceptions in this case, that decision is incorrect and should not be followed.

i. The Facts Do Not Support Any Stark Law Exception

In any event, even if the government were required to plead, as part of its *prima facie* case, that certain Stark Law exceptions³ do not apply or cannot be met, the government's Complaint easily clears that hurdle. Specifically, SEMC's indirect compensation arrangement with Dr. Agnihotri fails to satisfy the Stark Law's exception for indirect compensation arrangements found at 42 C.F.R. § 411.357(p) because, among other things, (1) the compensation the defendants paid to Dr. Agnihotri was not consistent with, or exceeded (depending on the requirements of the applicable exception) fair market value ("FMV"), *and* (2) the defendants determined the compensation in a manner that took into account the volume or value of the physician's referrals to the hospital.

FMV. With respect to FMV, the Complaint alleges in detail that SMG paid Dr. Agnihotri aggregate compensation in excess of FMV each year from 2013 through 2022. The compensation that the defendants now argue satisfied FMV, actually exceeded the defendants' own contemporaneous internal guidance, which required written justification for any compensation above the 75th percentile. *See* Compl. ¶¶ 133–41, Exs. 12, 14. Dr. Agnihotri's compensation in fact far exceeded the 90th percentile for cardiovascular surgeons in the eastern region of the United States based on the Medical Group Management Association ("MGMA")

³ The defendants cast their argument in terms of a "Stark Law safe harbor." The regulations refer to these provisions as "exceptions" rather than "safe harbors," see 42 C.F.R. § 411.357, so the government will use the term "exceptions."

benchmarking⁴ (the same standard used by defendants). *See* Compl. ¶¶ 100–02, 138.

At the appropriate time, the government will present its own FMV assessment evidence through expert testimony, but it need not plead the substance of that testimony to survive a motion to dismiss. “A plaintiff need not set forth allegations of expert opinions ... or other specific evidence at the pleading stage. The Federal Rules of Civil Procedure simply do not require that level of detail or a forecasting of the plaintiff’s anticipated evidence.” *James v. Subaru of Am., Inc.*, No. 1:19CV00021, 2020 WL 250514, at *2 (W.D. Va. Jan. 16, 2020). Whatever the ultimate factfinder concludes with respect to these opinions and the related facts, the Complaint obviously pleads a set of facts that at least could lead to the conclusion that the defendants paid Dr. Agnihotri aggregate compensation that exceeded FMV (a requirement that, again, does not exist at the pleading stage).

The defendants argue that Dr. Agnihotri’s high compensation was FMV because it was justified by his role as Chief of Cardiac Surgery, which in their view also justified compensating him for surgeries performed by others. ECF No. 97 at 15. This argument is not appropriate for a motion to dismiss. Even so, this justification is belied by the defendants’ own agreement with Dr. Agnihotri, which expressly stated that the administrative services portion of his base salary *fully compensated him* for his role as Chief of Cardiac Surgery. *See* Compl. Ex. 2 (“SMG shall pay Physician as consideration in full for the Physician’s provision and performance hereunder of the Administrative Duties [as Chief] a fee of One Hundred and Fifty Thousand Dollars (\$150,000) per year (the ‘Fee’).”). Having agreed in their contract with Dr. Agnihotri that the “full” consideration for such services was \$150,000, the defendants cannot now plausibly claim

⁴ The MGMA, an independent medical industry organization, provides benchmarking for physician compensation based on physician specialty and locality. Hospitals frequently use MGMA benchmarking when assessing FMV. Compl. ¶ 97.

that those same services justified increasing his Incentive Compensation based on surgeries performed by others in the Division.

Volume/Value. The defendants argue that Dr. Agnihotri's Incentive Compensation is not subject to the volume/value requirement because it is a "productivity bonus." ECF No. 97 at 4, 10–12. The defendants' argument improperly suggests that Dr. Agnihotri's Incentive Compensation was permissible under the "bona fide employment relationships" exception, which under certain circumstances permits payments "*by an employer to a physician*" for "a productivity bonus based on services performed personally by the physician." 42 U.S.C. § 1395nn(e)(2) (emphasis added); ECF No. 97, 9–10 (citing same). But the Complaint alleges a Stark Law violation based upon the *indirect* compensation arrangement between SEMC and Dr. Agnihotri, not the direct compensation arrangement between SMG and Dr. Agnihotri. Compl. ¶ 4; ECF No. 97 at 7 (acknowledging that the government's Stark Law theory is predicated upon an indirect compensation arrangement, not a direct compensation arrangement). The bona fide employment exception is not applicable to the *indirect* compensation arrangement between SEMC and Dr. Agnihotri. See 42 C.F.R. § 411.354(c)(4).⁵

Dr. Agnihotri's Incentive Compensation, moreover, could not qualify for any "productivity bonus" exception, even if it applied, because it was not based *solely* on his personal productivity. See 85 Fed. Reg. 77492, 77539 (Dec. 2, 2020) (reaffirming that

⁵ The "physician incentive plan" exception to the Stark Law, 42 C.F.R. § 411.357, also is inapplicable here. "Physician incentive plan means any compensation arrangement between an entity (or downstream contractor) and a physician or physician group that may directly or indirectly have the effect of **reducing or limiting** services furnished with respect to individuals enrolled with the entity." 42 C.F.R. § 411.351 (emphasis added). This exception is designed for managed care scenarios, in which a physician or physician group is paid on a per-patient basis rather than a fee-for-service basis. Here, Dr. Agnihotri's Incentive Compensation had the effect of incentivizing services, not reducing or limiting services.

compensation does not take into account the volume or value of referrals if the compensation is “tied *solely* to the physician’s personal productivity.”) (emphasis added). Instead, his agreements required that for his surgeries to count towards his Incentive Compensation he had to use an operating room at SEMC. As his agreements make clear, if Dr. Agnihotri personally performed office visits, he would not earn Incentive Compensation for those services. Similarly, if Dr. Agnihotri personally performed surgeries at any other hospital, he would not earn Incentive Compensation for those surgeries. The additional requirement that the surgeries be performed at SEMC means that the compensation was not tied *solely* to Dr. Agnihotri’s personal productivity; instead, it was tied only to the part of his practice that resulted in referrals to SEMC.

The defendants’ argument is even less compelling when considering the purposes of the Stark Law. If a “productivity bonus” with a requirement that services be performed at a particular DHS entity were permissible under the Stark Law, as the defendants’ contend, it could skew the physician’s incentives towards performing procedures that resulted in surgeries rather than non-surgical services. That result is the opposite of what the Stark Law is intended to prohibit. The Court should reject the defendants’ attempt to now re-label his Incentive Compensation as a “productivity bonus” and should focus on the underlying reality, as alleged, that Dr. Agnihotri’s compensation took into account the volume of his referrals to SEMC.⁶

Defendants also argue that Dr. Agnihotri’s Incentive Compensation was tied to the number of “procedures,” not referrals, and that these procedures only “corresponded” to the DHS

⁶ The government did not state that compensation based on wRVUs never takes into account the volume or value of referrals. *Compare* ECF No. 97 at 11 *with* Compl. ¶ 112 n. 20. A compensation arrangement under which a physician receives a productivity bonus payment only when the physician’s personally performed wRVUs are furnished at a particular DHS entity would raise the same issue as Dr. Agnihotri’s Incentive Compensation.

referrals. ECF No. 97 at 11–12. The absence of the term “referral” in Dr. Agnihotri’s Incentive Compensation provision does not mean that the defendants’ formula for calculating the Incentive Compensation did not include referrals; the defendants simply used different words for the same concept. CMS has publicly rejected the type of “magic words” argument that the defendants now advance. Specifically, a comment to a proposed rule urged CMS to disqualify payment arrangements only where “the physician’s referrals are a written or otherwise expressly articulated variable in the formula for calculating the compensation paid to a physician.” 85 Fed. Reg. 77492, 77542–43 (Dec. 2, 2020). CMS declined to adopt the suggestion and stated:

Compensation paid to a physician takes into account the volume or value of referrals **if the formula used to calculate the physician’s (or immediate family member’s) compensation includes the physician’s referrals to the entity as a variable**, resulting in an increase or decrease in the physician’s (or immediate family member’s) compensation that positively correlates with the number or value of the physician’s referrals to the entity, **regardless of whether the formula is written in a particular place or manner.**

Id. at 77543 (emphasis added). The Complaint alleges that the formula the defendants used to calculate Dr. Agnihotri’s Incentive Compensation included his referrals to SEMC as a variable that resulted in an increase in his compensation that directly relates to the number of his referrals to SEMC. Compl. ¶¶ 68–74, 78–79, 81, 105–11.

The defendants bear the burden to prove any affirmative defenses, and they cannot establish an affirmative defense based on the face of the Complaint. To the contrary, the government has pled facts that show that the defendants cannot meet critical elements — FMV and the prohibition on aggregate compensation that varies based on the volume or value of referrals — required to satisfy any of the Stark Law’s statutory or regulatory exceptions.

II. The Complaint Adequately Pled Materiality Under the FCA

The defendants argue that the government has not sufficiently pled materiality. ECF No.

97 at 16. To the contrary, under the Supreme Court’s holistic approach to assessing materiality under the FCA, the government adequately pled that compliance with the Stark Law is material to Medicare’s payment decision. In *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 136 S. Ct. 1989 (2016), the Supreme Court reaffirmed that, under the FCA, “the term ‘material’ means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.” *Id.* at 2002 (quoting 31 U.S.C. § 3729(b)(4)). In *Escobar*, the Supreme Court identified a variety of factors bearing on the materiality inquiry, including whether the requirement is a condition of payment, the violation goes to the “essence of the bargain,” the violation is significant or “minor or insubstantial,” and the government took action in this or other cases when it had knowledge of similar violations. *Id.* at 2003–04 & n.5. “[C]ourts are to conduct a **holistic approach** to determining materiality in connection with a payment decision, with no one factor being necessarily dispositive.” *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 109 (1st Cir. 2016) (emphasis added).

Stark Law compliance is material to the United States’ decision to reimburse healthcare claims. First, the government’s decision to identify a provision as a condition of payment is strong evidence of materiality. *Escobar*, 136 S. Ct. at 2003–04. “Congress did not merely label the Stark Law a condition of payment, but imposed it as a mandatory condition, which is the strongest possible indication of materiality.” *Wheeling*, 2019 WL 4478843, at *8. *See* 42 U.S.C. §§ 1395nn(a)(1), (g)(1); 42 C.F.R. § 411.353(d); Compl. ¶¶ 173–74.

Second, the defendants’ Stark Law violations go to the essence of the bargain at issue here. When the government subsidizes medical care, it is bargaining for the provision of care that is untainted by financial conflicts of interest. Medicare offers a government “subsidy . . . with conditions,” and when “the conditions are not satisfied, nothing is due.” *Rogan*, 517 F.3d at

453. As the *Wheeling* Court found, the Stark Law goes to the “essence of Medicare’s bargain with participating healthcare providers” and violations are “not minor or insubstantial” because “defendants directly incentivized and paid physicians in return for increased referrals to Wheeling Hospital.” *Wheeling*, 2019 WL 4478843, at *9.

Third, the defendants’ violations were not minor or insubstantial. The Stark Law helps ensure that financial conflicts of interest do not influence medical decision-making. *See Tuomey I*, 675 F.3d at 397. As alleged, the defendants’ violations are the very type of financial conflicts that the Stark Law was meant to prohibit. The Stark Law was designed to act prophylactically; an enforcement action based on Stark Law violations does not then, as the defendants would have it, contain as a prerequisite the very outcome it seeks to prevent—patient harm.

Finally, the United States’ consistent and repeated pursuit of FCA claims for violations of the Stark Law demonstrates materiality here. Compl. ¶¶ 177–84; *see United States ex rel. Druding v. Care Alts.*, 81 F.4th 361, 375 n.15 (3d Cir. 2023) (reasoning that the government’s after-the-fact enforcement actions, not just its contemporaneous payment decisions, are relevant to the materiality inquiry).

The Complaint, for these reasons, has sufficiently pled facts to support the holistic determination that the Stark Law violations alleged here were material for FCA purposes. The defendants’ arguments against materiality provide no basis for a different conclusion. For example, the defendants are wrong that enforcement actions are irrelevant to materiality. ECF No. 97 at 17 (citing *United States v. Strock*, 982 F.3d 51, 63 (2d Cir. 2020)). Indeed, in the *Strock* opinion itself that the defendants cite, the Second Circuit stated that “purely post hoc enforcement actions can carry some weight in a materiality analysis.” 982 F.3d at 63–64. The Complaint’s allegations of enforcement actions support a finding of materiality and cannot

simply be categorically written off as the defendants propose. “[C]ourts have repeatedly held that alleged violations of the Stark Law . . . were material, including after *Escobar*.” *Wheeling*, 2019 WL 4478843, at *9 (collecting cases).

The defendants also argue that the alleged Stark Law violations cannot be material because CMS did not stop payment to SEMC during the government’s investigation. ECF No 97 at 18. But the government need not administratively suspend payment simply upon receipt of allegations of Stark Law violations. Courts have recognized that “Congress intended to allow the government to choose from a variety of remedies, both statutory and administrative, to combat fraud.” *United States ex rel. Onnen v. Sioux Falls Indep. Sch. Dist. No. 49-5*, 688 F.3d 410, 414–15 (8th Cir. 2012) (quotation marks omitted). The hospital industry would not want the government to cut off payments whenever a *qui tam* action is filed, and the defendants’ denial of the allegations cuts against their argument that the government’s continued payment during the investigation means that the conduct was not material. *Wheeling* at *7 (“This Court doubts that the hospital industry would warmly welcome a rule that required the Government to cut off hospital funding whenever a *qui tam* action is filed or forfeit its right to seek reimbursement. The Government does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing. To this day, defendants claim they did not have the requisite scienter to violate the FCA.”) (internal quotation marks omitted); *see also United States ex rel. Mackillop v. Grand Canyon Educ., Inc.*, 626 F. Supp. 3d 418, 450-51 (D. Mass. 2022) (rejecting the defendant’s summary judgment argument that the government’s lack of action is dispositive of materiality).

At the time the government intervened in this matter, the defendants had already ended

the unlawful scheme, so it would have made little sense to stop payment prospectively.⁷ The United States does not allege that the Stark Law violations are ongoing, and therefore would have no reason to stop payment to SEMC for services resulting from Dr. Agnihotri's referrals at this point. The United States has confirmed the materiality of the defendants' alleged violations by intervening in this case, where it seeks a judgment awarding appropriate financial remedies. *See Wheeling*, 2019 WL 4478843, at *10 (finding that the government's intervention in a FCA case "strongly militates in favor of materiality.")

III. The Complaint Adequately Pled Scienter Under the FCA

While Rule 9(b) imposes heightened pleading requirements in fraud cases, it allows that "knowledge, and other conditions of a person's mind may be alleged generally." This standard is met where plaintiffs "set forth specific facts that support an inference of fraud." *United States ex rel. Wilson v. Kellogg Brown & Root, Inc., et al.*, 525 F.3d 370, 379 (4th Cir. 2008); *see also Iqbal*, 556 U.S. at 686 (knowledge under 9(b) does not need to be plead with particularity, but must be plausibly alleged); *United States v. Berkeley Heartlab, Inc. et al.*, 225 F. Supp. 3d 487, 500 (D.S.C. 2016) (at the pleading stage "the Government need not prove scienter, it need only allege it"); *United States ex re. Baklid-Kunz v. Halifax Hosp. Med. Ctr., et al.*, No. 6:09-cv-1002-Orl-31DAB, 2012 WL 921147, at *6 (M.D. Fla. Mar. 19, 2022) (rejecting defense argument of insufficiently pled scienter in FCA case premised on Stark Law violations).

The United States has pled scienter in detail. Compl. ¶¶ 121–54. Steward provided training on the Stark Law and the FCA to employees of Steward, SEMC, and SMG. Compl.

⁷ Effective April 1, 2022, SMG and Dr. Agnihotri terminated the Incentive Compensation provision of Dr. Agnihotri's employment agreement. Compl. ¶ 83. The Relevant Period of the United States' allegations is January 1, 2013, through March 31, 2022. *Id.* at ¶ 6. The United States filed its Notice of Election to Intervene in Part and Decline in Part on September 5, 2023. ECF No. 47.

¶¶ 129–31, 142–47, and Exs. 12–14. Based on those trainings, the defendants knew “[a]ll financial arrangements with physicians or physician groups must meet fair market value.” Compl. ¶ 136 and Ex. 14. The SMG executive who signed Dr. Agnihotri’s original employment agreement understood that the “Stark [Law] is in place to prevent the taking into account the volume or value of referrals from referring physicians.” *Id.* ¶¶ 73, 143. SMG and Steward had internal policies and procedures designed to ensure that their physician employment agreements were FMV, but did not follow them with respect to Dr. Agnihotri’s employment agreement. *Id.* ¶¶ 135–37. Worse still, the defendants ignored concerns raised internally, by multiple SEMC executives, about the legality of Dr. Agnihotri’s compensation arrangement. Compl. ¶¶ 148–54.

The defendants argue that the Stark Law violation was not obvious enough, or that the internal concerns were not specific enough. ECF No. 97 at 19. None of the case law they cite supports drawing such distinctions at the pleading stage. In *United States ex rel. Modglin v. DJO Glob. Inc.*, 48 F. Supp. 3d 1362, 1405 (C.D. Cal. 2014), the issue was whether a warning from the FDA concerning the labeling for the defendants’ medical device would alert the defendants to a separate question of Medicare reimbursement for those devices. Here, the relevant scienter evidence addresses the Stark Law and FCA. These statutes, unlike the AKS, do not require proof of a willful violation; similarly, then, the defendants’ discussion of *McKesson* (an AKS case) is completely misplaced. *United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 154 (2d Cir. 2024). The third case the defendants cite does not even address scienter *at all*. See *United States ex rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (affirming dismissal for failure to plead the presentment of any actual claims to Medicare).

The defendants were deeply familiar with the Stark Law and FCA, avoided following their own procedures, and ignored internally raised concerns and information about the

misconduct alleged in this case. These allegations, at a minimum, support an inference that the defendants acted at least with reckless disregard if not actual knowledge.

VI. The Government is Entitled to Plead Alternative Theories

The Court should deny the defendant's motion to dismiss Counts III and IV stating common law causes of action because the government is entitled to plead alternative theories at this stage of the litigation. Parties "may set out 2 or more statements of a claim alternatively . . . either in a single count or in separate ones . . . [and may] state as many separate claims . . . as it has, regardless of consistency." Fed. R. Civ. P. 8(d)(2) and (3). "[I]t is accepted practice to pursue both theories [unjust enrichment and contract] at the pleadings stage." *Lass v. Bank of Am., N.A.*, 695 F. 3d 129, 140 (1st Cir. 2012). The defendants' citation, to *Teva*, 560 F. Supp. 3d at 423–24, does not support their argument. The court in that case quoted from an opinion dismissing common law claims at the summary judgment stage, not at the motion to dismiss stage. See *United States ex rel. Martino-Fleming v. South Bay Mental Health Ctrs.*, 540 F. Supp. 3d 103, 133 (D. Mass. 2021) (dismissing common law claims at the *summary judgment stage*); *South Bay*, 334 F. Supp. 3d 394 at 405 (denying a motion to dismiss stating, "The unjust enrichment claim may be pled against all defendants as an alternative theory of liability."). Alternative claims should not be dismissed in the early stages of the proceedings. See *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 130 (D. Mass. 2011) (the viability of a theory of unjust enrichment is an issue for later consideration).

CONCLUSION

For the reasons set forth above, the government respectfully requests that this Court deny the defendants' motion to dismiss in its entirety, or in the alternative, permit the government to amend its Complaint to ameliorate any pleading concerns or deficiencies.

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Respectfully submitted,

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